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| APPLICATION NO  | . Fi | ILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------|--------------|----------------------|---------------------|------------------|
| 10/537,787 06/06/2005                                   |      | Sofie Claeys | 2551-173 6696        |                     |                  |
| 23117   | 7590 | 09/27/2006   | EXAMINER             |                     | INER             |
|   |      | RHYE, PC     | SALMON, KATHERINE D  |                     |                  |
| 901 NORTH GLEBE ROAD, 11TH FLOOR<br>ARLINGTON, VA 22203 |      |              |                      | ART UNIT            | PAPER NUMBER     |
|   |      |              |                      | 1634                |                  |

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| ·  | Application No.   | Applicant(s)  |  |  |  |  |
|--|---|---------------|--|--|--|--|
|  | 10/537,787  | CLAEYS ET AL. |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit      |  |  |  |  |
|  | Katherine Salmon  | 1634          |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address  |   |               |  |  |  |  |
| Period for Reply   |   |               |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |               |  |  |  |  |
| Status   |   |               |  |  |  |  |
| 1) Responsive to communication(s) filed on <u>06 Ju</u>  | <u>ine 2005</u> .   |               |  |  |  |  |
| .—   | •—  |               |  |  |  |  |
| • -  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |               |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |               |  |  |  |  |
| Disposition of Claims  |   |               |  |  |  |  |
| 4)⊠ Claim(s) <u>1-15</u> is/are pending in the application.  |   |               |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |               |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |               |  |  |  |  |
| 6) Claim(s) is/are rejected.   |   |               |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |               |  |  |  |  |
| 8) Claim(s) <u>1-15</u> are subject to restriction and/or election requirement.  |   |               |  |  |  |  |
| Application Papers   |   |               |  |  |  |  |
| 9) The specification is objected to by the Examine   | r.  |               |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.   |   |               |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |               |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |               |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |               |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |               |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |               |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |               |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |               |  |  |  |  |
| <ul><li>2. Certified copies of the priority documents have been received in Application No</li><li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li></ul>   |   |               |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |               |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |               |  |  |  |  |
|  |   |               |  |  |  |  |
| Attachment(s)  |   |               |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary<br>Paper No(s)/Mail Da   |               |  |  |  |  |
| <ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO/SB/08)</li> </ul>  | 5) D Notice of Informal P   |               |  |  |  |  |
| Paper No(s)/Mail Date  | 6) Other:   |               |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7and 15, drawn to an isolated nucleic acid molecule, probes, and a kit.

Group II, claim(s) 8-14, drawn to a method for detecting or identifying Staphylococcus species.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-II, is a fragment of at least 20 contiguous nucleotide of SEQ ID NO. 2. Groups I-II do not share a special technical feature over the art because Gurtler (GenBank Accession Number U11789 September 16, 1995) teaches a *Staphylococcus aureus* isolate which is 100% identical to SEQ ID No. 2 at greater than 20 contiguous nucleotides (Nucleotides 282-424 are identical to the instant applications SEQ ID NO. 2 nucleotides 1-143). Therefore, Gurtler teaches all the limitations of Claim 3. Therefore the

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technical feature of at least 20 contiguous nucleotides of SEQ ID No. 2 fails to make a contribution over the prior art; therefore, there is no special technical feature between Groups I-II.

3. **Further Restriction Requirement:** Additionally, each group named above is subject to further restriction. For Groups I-II, the applicant must select a **specific set of two probes**. The probes listed in the above groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the probes share a common property or activity. Each sequence is drawn to a structurally distinct nucleic acid molecule.

Moreover, since the polynucleotides are structurally distinct, they fail to share a common structure, i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since all nucleic acid molecules share it. Therefore the 43 polynucleotides molecules do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that polynucleotide fragments are derived from the same source is not sufficient to meet the criteria for unity of invention. The polynucleotides fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotides molecules claimed does not meet the requirement of unity of invention.

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4. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

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dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon

Examiner
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BJ FORMAN, PH.D. PRIMARY EXAMINER